

Applicant: Matthias G. von Herrath  
Application No.: 09/336,672  
Filed: June 17, 1999  
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**In the Claims**

Please cancel claims 62, 63, 66-68, 80, 81 and 83 without prejudice.

Please amend claims 40, 45, 46, 58, 59, 69, 72, 74, 75, 76, 77, 78 and 82 as follows:

Claims 1-39 (Cancelled)

40. (Currently Amended) An immunomodulating composition for treating ~~a condition or autoimmune process associated with~~ autoimmune diabetes, said composition comprising one or more nucleic acid construct encoding GAD self-antigen and IL-10 in a pharmaceutically acceptable carrier.

41. (Previously Added) The composition of claim 40, wherein the autoimmune diabetes is type I diabetes.

Claims 42-44 (Cancelled)

45. (Currently Amended) The composition of claim [44] 40, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the IL-10.

46. (Currently Amended ) The composition of claim 45, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

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Claims 47-53 (Cancelled)

54. (Previously Amended) A method for treating autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid construct encoding GAD self-antigen and IL-10 in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the IL-10 in the subject treats the autoimmune diabetes.

55. (Previously Added) The method of claim 54, wherein the subject is a human.

Claims 56-57 (Cancelled)

58. (Currently Amended ) The method of claim 54, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

59. (Currently Amended ) The method of claim 58, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

60. (Previously Added) The method of claim 54, wherein the treatment comprises controlling the blood sugar of the subject.

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61. (Previously Added) The method of claim 54, wherein the treatment comprises induction of T-cells reactive to the self-antigen.

Claim 62-68 (Cancelled)

69. (Currently amended) An immunomodulating composition for treating ~~a condition or autoimmune process associated with~~ autoimmune diabetes, said composition comprising one or more nucleic acid construct encoding an insulin B-chain self-antigen and a cytokine selected from the group consisting of IL-10, IL-4, and a combination thereof, in a pharmaceutically acceptable carrier.

70. (Previously Added) The composition of claim 69, wherein the autoimmune diabetes is type I diabetes.

71. (Currently Amended) The composition of claim ~~71~~ 69, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

72. (Currently Amended) The composition of claim ~~72~~ 71, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

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73. (Previously Added) A method for treating autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid construct encoding insulin B chain self-antigen and a cytokine selected from the group consisting of IL-4, IL-10, and a combination thereof, in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the cytokine in the subject treats the autoimmune diabetes.

74. (Currently Amended) The method of claim ~~76~~ 73, wherein the subject is a human.

75. (Currently Amended) The method of claim ~~76~~ 73, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

76. (Currently Amended) The method of claim ~~78~~ 75, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

77. (Previously Amended) The method of claim ~~74~~ 73 wherein the treatment comprises controlling the blood sugar of the subject.

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78. (Previously Amended) A method for treating an autoimmune process associated with autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid ~~construct~~ encoding insulin B-chain self-antigen and a cytokine selected from the group consisting of IL-4, IL-10, and a combination thereof, in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the cytokine in the subject treats the autoimmune process associated with the autoimmune diabetes.

79. (Previously Added) The method of claim 78, wherein the subject is a human.

Claims 80-81 (Cancelled)

82. (Currently Amended) The method of claim ~~80~~ 78, wherein the treatment comprises induction of T-cells reactive to the self-antigen.

83. (Currently Amended) The method of claim ~~80~~ 73, wherein the nucleic acid construct is naked DNA.